agglutination reactions are provided. In another example, improved reagents for agglutination reactions are provided. In another example, improved devices for performing or analyzing agglutination reactions are provided. Additional improvements are also provided and the disclosure includes additional aspects. Multiple improvements disclosed herein may be used together.

In one ~~aspect~~example, a method for determining the presence of an antibody in a biological sample is provided, wherein the antibody binds selectively to a viral particle, and the method includes the steps of: (a) incubating a mixture of erythrocytes, the viral particle and the biological sample suspected of containing the antibody, under conditions permitting agglutination of the erythrocytes via interaction with the viral particle; and (b) detecting whether agglutination occurs in the mixture, wherein the absence of agglutination indicates the presence of the antibody, and wherein said steps (a) – (b) take place in less than one hour. In one aspect, there is provided a method for determining the presence of an antibody in a biological sample, wherein said antibody binds selectively to a viral particle, the method comprising: (a) incubating a mixture of erythrocytes, the viral particle, and the biological sample suspected of containing said antibody, under conditions permitting agglutination of the erythrocytes via interaction with said viral particle; and (b) detecting whether said agglutination occurs in said mixture, wherein the absence of said agglutination indicates the presence of said antibody, wherein the presence of said agglutination is evidenced by formation of erythrocyte-viral particle clusters, wherein a cluster comprises a contiguous distribution of two or more erythrocytes having center-to-center distances between said erythrocytes of up to two times erythrocyte diameter, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises: (i) capturing a plurality of images of said clusters at different locations of said imaging region with said optical device; (ii) calculating the size of said clusters based on the center-to-center distances between individual erythrocytes captured in each of said images; and (iii) detecting the occurrence of said agglutination based on analysis of said cluster sizes calculated from the plurality of images obtained using the optical device, wherein said steps (a) – (b) take place in less than one hour, and wherein the viral particle is hemagglutinating viral particle. In another aspect, there is provided a method for determining the presence of an antibody in a biological sample, where said antibody binds selectively to a viral particle, the method comprising: (a) incubating a mixture of erythrocytes, the viral particle, and the biological sample suspected of containing said antibody, under conditions permitting agglutination of the erythrocytes via interaction with said viral particle; and (b) capturing with the aid of an optical device an image of said mixture to determine whether or not an erythrocyte-viral particle cluster has been formed, wherein the formation of said erythrocyte –viral particle cluster is determined by assessing center-to-center distance between individual erythrocytes captured in said image, wherein the presence of an erythrocyte –viral particle cluster in said image indicates the occurrence of said agglutination and lack of detectable amount of said antibody, and wherein the absence of said cluster indicates the lack of said agglutination and the presence of detectable amount of said antibody, wherein the presence of said agglutination is evidenced by formation of erythrocyte-viral particle clusters, wherein a cluster comprises a contiguous distribution of two or more erythrocytes having center-to-center distances between said erythrocytes of up to two times erythrocyte diameter, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises: (i) calculating the size of said clusters based on the center-to-center distances between individual erythrocytes captured in said image; and (ii) detecting the occurrence of said agglutination based on analysis of said cluster sizes calculated from the image obtained using the optical device, wherein the viral particle is hemagglutinating viral particle. In another aspect, there is provided a method for determining the presence of an antibody in a biological sample, wherein said antibody binds selectively to a viral particle, the method comprising: (a) incubating a mixture of erythrocytes, the viral particle, and the biological sample suspected of containing said antibody, under conditions permitting agglutination of the erythrocytes via interaction with said viral particle; (b) concurrent with or subsequent to (a), providing the mixture in a vessel having an opening at the top of the vessel and interior conical shape at the bottom of the vessel; (c) tilting the vessel such that after tilting, at least a portion of the mixture is closer to the opening at the top of the vessel than prior to the tilting, and wherein at least a portion of the sample remains in the vessel after the tilting; and (d) capturing with the aid of an optical device an image of said mixture, wherein the image of erythrocytes within the tilted vessel may be used to determine the presence or amount of said antibody in the sample, wherein the presence of said agglutination is evidenced by formation of erythrocyte-viral particle clusters, wherein a cluster comprises a contiguous

distribution of two or more erythrocytes having center-to-center distances between said erythrocytes of up to two times erythrocyte diameter, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises: (i) capturing a plurality of images of said clusters at different locations of said imaging region with said optical device; (ii) calculating the size of said clusters based on the center-to-center distances between individual erythrocytes captured in each of said images; and (iii) detecting the occurrence of said agglutination based on analysis of said cluster sizes calculated from the plurality of images obtained using the optical device, and wherein the viral particle is hemagglutinating viral particle. In yet another aspect, there is provided a method for determining the presence of an antibody in a biological sample, wherein said antibody binds selectively to an agglutinating viral particle, the method comprising: (a) incubating a mixture of visualization particles, the agglutinating particle, and the biological sample suspected of containing said antibody, under conditions permitting agglutination of the visualization particle via interaction with said agglutinating viral particle; and (b) detecting whether said agglutination occurs in said mixture, wherein the absence of said agglutination indicates the presence of said antibody, wherein the presence of said agglutination is evidenced by formation of erythrocyte-agglutinating viral particle clusters, wherein a cluster comprises a contiguous distribution of two or more erythrocytes having center-to-center distances between said erythrocytes of up to two times erythrocyte diameter, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises: (i) capturing a plurality of images of said clusters at different locations of said imaging region with said optical device; (ii) calculating the size of said clusters based on the center-to-center distances between individual erythrocytes captured in each of said images; and (iii) detecting the occurrence of said agglutination based on analysis of said cluster sizes calculated from the plurality of images obtained using the optical device, wherein said steps (a) – (b) take place in less than one hour. In a further aspect, there is provided a method for determining the presence of an antibody in a biological sample, wherein said antibody binds selectively to an agglutinating viral particle, the method comprising: (a) incubating a mixture of visualization particles, the agglutinating viral particle, and the biological sample suspected of containing said antibody, under conditions permitting agglutination of the visualization particle via interaction with said agglutinating viral particle; (b) concurrent with or subsequent to (a), providing the mixture in a vessel having an opening at the top of the vessel and interior conical shape at the bottom of the vessel; (c) tilting the vessel such that after tilting, at least a portion of the mixture is closer to the opening at the top of the vessel than prior to the tilting, and wherein at least a portion of the sample remains in the vessel after the tilting; and (d) capturing with the aid of an optical device an image of said mixture, wherein the image of visualization particles within the tilted vessel may be used to determine the presence or amount of said antibody in the sample, wherein the presence of said agglutination is evidenced by formation of erythrocyte-agglutinating viral particle clusters, wherein a cluster comprises a contiguous distribution of two or more erythrocytes having center-to-center distances between said erythrocytes of up to two times erythrocyte diameter, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises: (i) capturing a plurality of images of said clusters at different locations of said imaging region with said optical device; (ii) calculating the size of said clusters based on the center-to-center distances between individual erythrocytes captured in each of said images; and (iii) detecting the occurrence of said agglutination based on analysis of said cluster sizes calculated from the plurality of images obtained using the optical device. In another related but separate ~~aspect~~example, the method includes (a) incubating a mixture of erythrocytes, a viral particle, and a biological sample suspected of containing the antibody, under conditions permitting agglutination of the erythrocytes via interaction with the viral particle; and (b) capturing with the aid of an optical device an image of the mixture, wherein the presence of an erythrocyte –viral particle cluster in the image indicates the occurrence of agglutination and lack of detectable amount of the antibody, and wherein the absence of the cluster indicates the lack of agglutination and the presence of a detectable amount of the antibody. In some examples, a microscopic image of the mixture is obtained.

In another example, a method for determining the presence of a viral particle in a biological sample is provided, wherein the method includes: (a) incubating a mixture of erythrocytes or modified red blood cells, a biological sample suspected of containing the viral particle, under conditions permitting agglutination of the erythrocytes via interaction with the viral particle; and (b) detecting whether agglutination occurs in the mixture, wherein the presence of agglutination indicates the presence of the viral particle, and wherein steps

(a) – (b) take place in less than one hour. In a related but separate example, the method of determining the presence of a viral particle in a biological sample includes: (a) incubating a mixture of erythrocytes, a biological sample suspected of containing the viral particle, under conditions permitting agglutination of the erythrocytes via interaction with the viral particle; and (b) capturing with the aid of an optical device an image of the mixture, wherein the presence of an erythrocyte –viral particle cluster in the image indicates the occurrence of agglutination and the presence of detectable amount of the viral particle, and wherein the absence of the cluster indicates the lack of agglutination and the lack of detectable amount of the viral particle. In some examples, a microscopic image of the mixture is obtained.

[0008] In another aspect, the present invention refers to a method for determining the effective immunization of a subject, comprising: (a) incubating a mixture of erythrocytes, a viral particle, and a biological sample obtained from the subject that has been immunized with a first dosage of a first vaccine against the viral particle, under conditions permitting agglutination of the erythrocytes via interaction with said viral particle; and (b) determining the concentration of an antibody against said virus in said sample based on the clusters formed by the agglutination of the erythrocytes, wherein the presence of said agglutination is evidenced by formation of erythrocyte-viral particle clusters, wherein a cluster comprises a contiguous distribution of two or more erythrocytes having center-to-center distances between said erythrocytes of up to two times erythrocyte diameter, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises: (i) capturing a plurality of images of said clusters at different locations of said imaging region with said optical device; (ii) calculating the size of said clusters based on the center-to-center distances between individual erythrocytes captured in each of said images; and (iii) detecting the occurrence of said agglutination based on analysis of said cluster sizes calculated from the plurality of images obtained using the optical device, and wherein said steps (a) – (b) take place in less than one hour, and wherein the viral particle is hemagglutinating viral particle. In another example, a method for determining the effective immunization of a subject is provided, including: (a) obtaining a biological sample from a subject who has been immunized with a first dosage of a first vaccine against a viral particle; (b) incubating a mixture of erythrocytes, the viral particle, and the biological sample, under conditions permitting agglutination of the erythrocytes via interaction with the viral particle; and (c) determining the concentration of an antibody against the virus in the sample based on the clusters formed by the agglutination of the erythrocytes, and wherein said steps (b) – (c) take place in less than one hour. In another aspect, the present invention refers to a method for determining the effective immunization of a subject, comprising: (a) incubating a mixture of erythrocytes, a viral particle, and a biological sample obtained from the subject that has been immunized with a first dosage of a first vaccine against the viral particle, under conditions permitting agglutination of the erythrocytes via interaction with said viral particle; (b) capturing with the aid of an optical device an image of said mixture; and (c) determining the concentration of an antibody against said viral in said biological sample based on the clusters formed by the agglutination of the erythrocytes, wherein the presence of said agglutination is evidenced by formation of erythrocyte-viral particle clusters, wherein a cluster comprises a contiguous distribution of two or more erythrocytes having center-to-center distances between said erythrocytes of up to two times erythrocyte diameter, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises: (i) capturing a plurality of images of said clusters at different locations of said imaging region with said optical device; (ii) calculating the size of said clusters based on the center-to-center distances between individual erythrocytes captured in each of said images; and (iii) detecting the occurrence of said agglutination based on analysis of said cluster sizes calculated from the plurality of images obtained using the optical device, wherein the presence of an erythrocyte – viral particle cluster in said image indicates the occurrence of said agglutination and lack of detectable amount of said antibody, and wherein the absence of said cluster indicates the lack of said agglutination and the presence of detectable amount of said antibody, and wherein the viral particle is hemagglutinating viral particle. In one aspect, there is provided a method for determining the effective immunization of a subject, comprising: (a) incubating a mixture of visualization particles, an agglutinating viral particle, and a biological sample obtained from the subject that has been immunized with a first dosage of a first vaccine against the agglutinating viral particle, under conditions permitting agglutination of the visualization particles via interaction with said agglutinating viral particles; and (b) determining the concentration of an antibody against said agglutinating viral particle in said sample based on the clusters formed by the agglutination of the visualization particles, wherein the presence of said agglutination is evidenced by formation of erythrocyte-agglutinating viral particle clusters, wherein a cluster comprises a contiguous distribution of two or more erythrocytes having center-to-center distances between said erythrocytes of up to two times erythrocyte diameter, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises: (i) capturing a plurality of images of said clusters at different locations of said imaging region with said optical device; (ii) calculating the size of said clusters based on the center-to-center distances between individual erythrocytes captured in each of said images; and (iii) detecting the occurrence of said agglutination based on analysis of said cluster sizes

calculated from the plurality of images obtained using the optical device, and wherein said steps (a) – (b) take place in less than one hour. In another aspect, there is provided a method for determining the effective immunization of a subject, comprising: (a) incubating a mixture of visualization particles, an agglutinating viral particle, and a biological sample obtained from the subject that has been immunized with a first dosage of a first vaccine against the agglutinating viral particle, under conditions permitting agglutination of the visualization particles via interaction with said agglutinating viral particle; (b) capturing with the aid of an optical device an image of said mixture; and (c) determining the concentration of an antibody against said agglutinating viral particle in said biological sample based on the clusters formed by the agglutination of the visualization particles, wherein the presence of a visualization particle –agglutinating viral particle cluster in said image indicates the occurrence of said agglutination and lack of detectable amount of said antibody, and wherein the absence of said cluster indicates the lack of said agglutination and the presence of detectable amount of said antibody, wherein the presence of said agglutination is evidenced by formation of erythrocyte-agglutinating viral particle clusters, wherein a cluster comprises a contiguous distribution of two or more erythrocytes having center-to-center distances between said erythrocytes of up to two times erythrocyte diameter, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises: (i) calculating the size of said clusters based on the center-to-center distances between individual erythrocytes captured in said image; and (ii) detecting the occurrence of said agglutination based on analysis of said cluster sizes calculated from the image obtained using the optical device. In a related but separate example, the method includes (a) obtaining a biological sample from a subject that has been immunized with a first dosage of a first vaccine against a viral particle; (b) incubating a mixture of erythrocytes, the viral particle, and the biological sample, under conditions permitting agglutination of the erythrocytes via interaction with the viral particle; (c) capturing with the aid of an optical device an image of the mixture; and (d) determining the concentration of an antibody against the viral particle in said biological sample based on the clusters formed by the agglutination of the erythrocytes, wherein the presence of an erythrocyte –viral particle cluster in the image indicates the occurrence of agglutination and lack of detectable amount of the antibody, and wherein the absence of the cluster indicates the lack of agglutination and the presence of detectable amount of the antibody. In some examples, a microscopic image of the mixture is obtained.

[0009] In examples, the erythrocytes can be pre-fixed, e.g., by treatment with glutaraldehyde. Where desired, the erythrocytes may include turkey red blood cells or red cells from other non-human RBCs.

[0010] The viral particles detected by any of the subject methods can include any type of agglutinating virus. For example and without limitation, hepatitis B virus (HBV), hepatitis C virus (HCV), and any strain of influenza virus may be detected by methods disclosed herein. In some examples, antibodies detected by any of the methods disclosed herein can be against any type of agglutinating particle, such as agglutinating viruses. For example and without limitation, antibodies against HBV, HCV and any strains of influenza virus may be detected.

[0011] The biological sample utilized in any of the methods disclosed herein can be any suitable bodily fluid, processed or unprocessed, including but not limited to fresh or anti-coagulated whole blood, plasma and serum. In some instances, the plasma or serum is from a subject that has been administered with a vaccine against the viral particle. Where desired, the biological sample can be pre-treated with neuraminidase, for example, by incubating said biological sample with neuraminidase, for a suitable period of time such as less than 2 hours, 1 hour, 30 minutes, 20 minutes, 10 minutes, 5 minutes or even less.

CLAIMS

WHAT IS CLAIMED IS:

1. A method for determining the presence of an antibody in a biological sample, wherein said antibody binds selectively to a viral particle, the method comprising:

(a) incubating a mixture of erythrocytes, the viral particle, and the biological sample suspected of containing said antibody, under conditions permitting agglutination of the erythrocytes via interaction with said viral particle; and

(b) detecting whether said agglutination occurs in said mixture, wherein the absence of said agglutination indicates the presence of said antibody, wherein the presence of said agglutination is evidenced by formation of erythrocyte-viral particle clusters, wherein a cluster comprises a contiguous distribution of two or more erythrocytes having center-to-center distances between said erythrocytes of up to two times erythrocyte diameter, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises:

(i) capturing a plurality of images of said clusters at different locations of said imaging region with said optical device;

(ii) calculating the size of said clusters based on the center-to-center distances between individual erythrocytes captured in each of said images; and

(iii) detecting the occurrence of said agglutination based on analysis of said cluster sizes calculated from the plurality of images obtained using the optical device,

wherein said steps (a) – (b) take place in less than one hour, and wherein the viral particle is hemagglutinating viral particle.

2. The method of claim 1, wherein said erythrocytes are pre-fixed.

3. The method of claim 2, wherein said erythrocytes are pre-fixed by treatment with glutaraldehyde.

4. The method of any of claims 1-3, wherein said erythrocytes comprise turkey red blood cells.

5. The method of any of claims 1-4, wherein said viral particle comprises an influenza virus.

6. The method of any of claims 1-5, wherein said biological sample comprises plasma or serum.

7. The method of claim 6, wherein said plasma or serum is from a subject that has been administered with a vaccine against said viral particle.

8. The method of any of claims 1-7, wherein said biological sample is pre-treated with neuraminidase.

9. The method of claim 8, wherein said treatment is carried out by incubating said biological sample with neuraminidase, and wherein the final concentration of the neuraminidase in the mixture is between 0.1 and 1.5 U/L.

10. The method of claim 8, wherein said treatment is carried out by incubating said sample with active neuraminidase for less than 30 minutes.

11. The method of any of claims 1-10, wherein said biological sample is serially diluted prior to step (a).

12. The method of any of claims 1-11, wherein said steps (a) – (b) take place between about 30 to 60 minutes.

13. The method of claim 1, wherein said optical device comprises a camera.

14. The method of claim 13, wherein said optical device comprises a microscope.

15 The method of claim 13 or 14, wherein said imaging region resides in a microfluidic channel.

16. The method of any of claims 1-15, wherein said step (a) comprises incubating a mixture of said viral particle and said biological sample before adding said erythrocytes.

17. A method for determining the presence of an antibody in a biological sample, where said antibody binds selectively to a viral particle, the method comprising:

(a) incubating a mixture of erythrocytes, the viral particle, and the biological sample suspected of containing said antibody, under conditions permitting agglutination of the erythrocytes via interaction with said viral particle; and

(b) capturing with the aid of an optical device an image of said mixture to determine whether or not an erythrocyte-viral particle cluster has been formed, wherein the formation of said erythrocyte –viral particle cluster is determined by assessing center-to-center distance between individual erythrocytes captured in said image, wherein the presence of an erythrocyte – viral particle cluster in said image indicates the occurrence of said agglutination and lack of detectable amount of said antibody, and wherein the absence of said cluster indicates the lack of said agglutination and the presence of detectable amount of said antibody, wherein the presence of said agglutination is evidenced by formation of erythrocyte-viral particle clusters, wherein a cluster comprises a contiguous distribution of two or more erythrocytes having center-to-center distances between said erythrocytes of up to two times erythrocyte diameter, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises:

(i) calculating the size of said clusters based on the center-to-center distances between individual erythrocytes captured in said image; and

(ii) detecting the occurrence of said agglutination based on analysis of said cluster sizes calculated from the image obtained using the optical device,

wherein the viral particle is hemagglutinating viral particle.

18. The method of claim 17, wherein said step (a) comprising incubating a mixture of said viral particle and said biological sample prior to adding said erythrocytes .

19. A method for determining the effective immunization of a subject, comprising:

(a) incubating a mixture of erythrocytes, a viral particle, and a biological sample obtained from the subject that has been immunized with a first dosage of a first vaccine against the viral particle, under conditions permitting agglutination of the erythrocytes via interaction with said viral particle; and

(b) determining the concentration of an antibody against said virus in said sample based on the clusters formed by the agglutination of the erythrocytes, wherein the presence of said agglutination is evidenced by formation of erythrocyte-viral particle clusters, wherein a cluster comprises a contiguous distribution of two or more erythrocytes having center-to-center distances between said erythrocytes of up to two times erythrocyte diameter, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises:

(i) capturing a plurality of images of said clusters at different locations of said imaging region with said optical device;

(ii) calculating the size of said clusters based on the center-to-center distances between individual erythrocytes captured in each of said images; and

(iii) detecting the occurrence of said agglutination based on analysis of said cluster sizes calculated from the plurality of images obtained using the optical device

and wherein said steps (a) – (b) take place in less than one hour, and wherein the viral particle is hemagglutinating viral particle.

20. A method for determining the effective immunization of a subject, comprising:

(a) incubating a mixture of erythrocytes, a viral particle, and a biological sample obtained from the subject that has been immunized with a first dosage of a first vaccine against the viral particle, under conditions permitting agglutination of the erythrocytes via interaction with said viral particle;

(b) capturing with the aid of an optical device an image of said mixture; and

(c) determining the concentration of an antibody against said viral in said biological sample based on the clusters formed by the agglutination of the erythrocytes, wherein the presence of said agglutination is evidenced by formation of erythrocyte-viral particle clusters, wherein a cluster comprises a contiguous distribution of two or more erythrocytes having center-to-center distances between said erythrocytes of up to two times erythrocyte diameter, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises:

(i) capturing a plurality of images of said clusters at different locations of said imaging region with said optical device;

(ii) calculating the size of said clusters based on the center-to-center distances between individual erythrocytes captured in each of said images; and

(iii) detecting the occurrence of said agglutination based on analysis of said cluster sizes calculated from the plurality of images obtained using the optical device

wherein the presence of an erythrocyte –viral particle cluster in said image indicates the occurrence of said agglutination and lack of detectable amount of said antibody, and wherein the absence of said cluster indicates the lack of said agglutination and the presence of detectable amount of said antibody, and wherein the viral particle is hemagglutinating viral particle.

21. The method of claim 17, wherein said image is a microscopic image.

22. A method for determining the presence of an antibody in a biological sample, wherein said antibody binds selectively to a viral particle, the method comprising:

(a) incubating a mixture of erythrocytes, the viral particle, and the biological sample suspected of containing said antibody, under conditions permitting agglutination of the erythrocytes via interaction with said viral particle;

(b) concurrent with or subsequent to (a), providing the mixture in a vessel having an opening at the top of the vessel and interior conical shape at the bottom of the vessel;

(c) tilting the vessel such that after tilting, at least a portion of the mixture is closer to the opening at the top of the vessel than prior to the tilting, and wherein at least a portion of the sample remains in the vessel after the tilting; and

(d) capturing with the aid of an optical device an image of said mixture, wherein the image of erythrocytes within the tilted vessel may be used to determine the presence or amount of said antibody in the sample, wherein the presence of said agglutination is evidenced by formation of erythrocyte-viral particle clusters, wherein a cluster comprises a contiguous distribution of two or more erythrocytes having center-to-center distances between said erythrocytes of up to two times erythrocyte diameter, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises:

(i) capturing a plurality of images of said clusters at different locations of said imaging region with said optical device;

(ii) calculating the size of said clusters based on the center-to-center distances between individual erythrocytes captured in each of said images; and

(iii) detecting the occurrence of said agglutination based on analysis of said cluster sizes calculated from the plurality of images obtained using the optical device,

wherein the viral particle is hemagglutinating viral particle.

23. A method for determining the presence of an antibody in a biological sample, wherein said antibody binds selectively to an agglutinating viral particle, the method comprising:

(a) incubating a mixture of visualization particles, the agglutinating viral particle, and the biological sample suspected of containing said antibody, under conditions permitting agglutination of the visualization particle via interaction with said agglutinating viral particle; and

(b) detecting whether said agglutination occurs in said mixture, wherein the absence of said agglutination indicates the presence of said antibody, wherein the presence of said agglutination is evidenced by formation of erythrocyte-agglutinating viral particle clusters, wherein a cluster comprises a contiguous distribution of two or more erythrocytes having center-to-center distances between said erythrocytes of up to two times erythrocyte diameter, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises:

(i) capturing a plurality of images of said clusters at different locations of said imaging region with said optical device;

(ii) calculating the size of said clusters based on the center-to-center distances between individual erythrocytes captured in each of said images; and

(iii) detecting the occurrence of said agglutination based on analysis of said cluster sizes calculated from the plurality of images obtained using the optical device,

wherein said steps (a) – (b) take place in less than one hour.

24. The method of claim 23, wherein said visualization particles are microspheres.

25. The method of claim 23 or 24, wherein said biological sample comprises plasma or serum.

26. The method of claim 25, wherein said plasma or serum is from a subject that has been administered with a vaccine against said agglutinating viral particle.

27. The method of any of claims 23-26, wherein said biological sample is pre-treated with neuraminidase.

28. The method of claim 27, wherein said treatment is carried out by incubating said biological sample with neuraminidase, and wherein the final concentration of the neuraminidase in the mixture is between 0.1 and 1.5 U/L.

29. The method of claim 28, wherein said treatment is carried out by incubating said sample with active neuraminidase for less than 30 minutes.

30. The method of any of claims 23-29, wherein said biological sample is serially diluted prior to step (a).

31. The method of any of claims 23-30, wherein said steps (a) – (b) take place in between about 30 to 60 minutes.

32. The method of any of claims 23-31, wherein the presence of said agglutination is evidenced by formation of visualization particle-agglutinating viral particle clusters, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises:

(i) capturing a plurality of images of said clusters at different locations of said imaging region with the optical device; and

(ii) detecting the occurrence of said agglutination based on analysis of said images.

33. The method of claim 32, wherein said optical device comprises a camera.

34. The method of claim 32, wherein said optical device comprises a microscope.

35. The method of any of claims 32-34, wherein said imaging region resides in a microfluidic channel.

36. The method of any of claims 32-35, wherein said analysis comprises calculating the size of said clusters based on the center-to-center distance of individual erythrocytes captured in each of said images.

37. The method of any of claims 23-26, wherein said step (a) comprises incubating a mixture of said viral particle and said biological sample before adding said erythrocytes.

38. A method for determining the effective immunization of a subject, comprising:

(a) incubating a mixture of visualization particles, an agglutinating viral particle, and a biological sample obtained from the subject that has been immunized with a first dosage of a first vaccine against the agglutinating viral particle, under conditions permitting agglutination of the visualization particles via interaction with said agglutinating viral particles; and

(b) determining the concentration of an antibody against said agglutinating viral particle in said sample based on the clusters formed by the agglutination of the visualization particles, wherein the presence of said agglutination is evidenced by formation of erythrocyte-agglutinating

viral particle clusters, wherein a cluster comprises a contiguous distribution of two or more erythrocytes having center-to-center distances between said erythrocytes of up to two times erythrocyte diameter, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises:

(i) capturing a plurality of images of said clusters at different locations of said imaging region with said optical device;

(ii) calculating the size of said clusters based on the center-to-center distances between individual erythrocytes captured in each of said images; and

(iii) detecting the occurrence of said agglutination based on analysis of said cluster sizes calculated from the plurality of images obtained using the optical device

and wherein said steps (a) – (b) take place in less than one hour.

39. A method for determining the effective immunization of a subject, comprising:

(a) incubating a mixture of visualization particles, an agglutinating viral particle, and a biological sample obtained from the subject that has been immunized with a first dosage of a first vaccine against the agglutinating viral particle, under conditions permitting agglutination of the visualization particles via interaction with said agglutinating viral particle;

(b) capturing with the aid of an optical device an image of said mixture; and

(c) determining the concentration of an antibody against said agglutinating viral particle in said biological sample based on the clusters formed by the agglutination of the visualization particles,

wherein the presence of a visualization particle –agglutinating viral particle cluster in said image indicates the occurrence of said agglutination and lack of detectable amount of said antibody, and wherein the absence of said cluster indicates the lack of said agglutination and the presence of detectable amount of said antibody, wherein the presence of said agglutination is evidenced by formation of erythrocyte-agglutinating viral particle clusters, wherein a cluster comprises a contiguous distribution of two or more erythrocytes having center-to-center distances between said erythrocytes of up to two times erythrocyte diameter, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises:

(i) calculating the size of said clusters based on the center-to-center distances between individual erythrocytes captured in said image; and

(ii) detecting the occurrence of said agglutination based on analysis of said cluster sizes calculated from the image obtained using the optical device.

40. The method of claim 38 or 39, wherein said subject has been immunized with a first and a second dosage of said first vaccine against said agglutinating viral particle if the concentration of said antibody is lower than a predetermined level.

41. The method of claim 38 or 39, wherein said subject has been immunized with a first dosage of a first vaccine against said agglutinating viral particle and a second vaccine against said agglutinating viral particle if the concentration of said antibody is lower than a predetermined level.

42. The method of any of claims 17, 20 and 39, wherein said image is a microscopic image.

43. A method for determining the presence of an antibody in a biological sample, wherein said antibody binds selectively to an agglutinating viral particle, the method comprising:

(a) incubating a mixture of visualization particles, the agglutinating viral particle, and the biological sample suspected of containing said antibody, under conditions permitting agglutination of the visualization particle via interaction with said agglutinating viral particle;

(b) concurrent with or subsequent to (a), providing the mixture in a vessel having an opening at the top of the vessel and interior conical shape at the bottom of the vessel;

(c) tilting the vessel such that after tilting, at least a portion of the mixture is closer to the opening at the top of the vessel than prior to the tilting, and wherein at least a portion of the sample remains in the vessel after the tilting; and

(d) capturing with the aid of an optical device an image of said mixture, wherein the image of visualization particles within the tilted vessel may be used to determine the presence or amount of said antibody in the sample, wherein the presence of said agglutination is evidenced by formation of erythrocyte-agglutinating viral particle clusters, wherein a cluster comprises a contiguous distribution of two or more erythrocytes having center-to-center distances between said erythrocytes of up to two times erythrocyte diameter, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises:

(i) capturing a plurality of images of said clusters at different locations of said imaging region with said optical device;

(ii) calculating the size of said clusters based on the center-to-center distances between individual erythrocytes captured in each of said images; and

(iii) detecting the occurrence of said agglutination based on analysis of said cluster sizes calculated from the plurality of images obtained using the optical device.

CLAIMS

WHAT IS CLAIMED IS:

1. A method for determining the presence of an antibody in a biological sample, wherein said antibody binds selectively to a viral particle, the method comprising:

(a) incubating a mixture of erythrocytes, the viral particle, and the biological sample suspected of containing said antibody, under conditions permitting agglutination of the erythrocytes via interaction with said viral particle; and

(b) detecting whether said agglutination occurs in said mixture, wherein the absence of said agglutination indicates the presence of said antibody,

wherein said steps (a) – (b) take place in less than one hour.

2. The method of claim 1, wherein said erythrocytes are pre-fixed.

3. The method of claim 2, wherein said erythrocytes are pre-fixed by treatment with glutaraldehyde.

4. The method of any of claims 1-3, wherein said erythrocytes comprise turkey red blood cells.

5. The method of any of claims 1-4, wherein said viral particle comprises an influenza virus.

6. The method of any of claims 1-5, wherein said biological sample comprises plasma or serum.

7. The method of claim 6, wherein said plasma or serum is from a subject that has been administered with a vaccine against said viral particle.

8. The method of any of claims 1-7, wherein said biological sample is pre-treated with neuraminidase.

9. The method of claim 8, wherein said treatment is carried out by incubating said biological sample with neuraminidase, and wherein the final concentration of the neuraminidase in the mixture is between 0.1 and 1.5 U/L.

10. The method of claim 8, wherein said treatment is carried out by incubating said sample with active neuraminidase for less than 30 minutes.

11. The method of any of claims 1-10, wherein said biological sample is serially diluted prior to step (a).

12. The method of any of claims 1-11, wherein said steps (a) – (b) take place between about 30 to 60 minutes.

13. The method of any of claims 1-12, wherein the presence of said agglutination is evidenced by formation of erythrocyte-viral particle clusters, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprising:

(i) capturing a plurality of images of said clusters at different locations of said imaging region with the optical device; and

(ii) detecting the occurrence of said agglutination based on analysis of said images.

14. The method of claim 13, wherein said optical device comprises a camera

15. The method of claim 13 or 14, wherein said optical device comprises a microscope.

16. The method of any of claims 13-15, wherein said imaging region resides in a microfluidic channel.

17. The method of any of claims 13-16, wherein said analysis comprises calculating the size of said clusters based on the center-to-center distance of individual erythrocytes captured in each of said images.

18. The method of any of claims 1-17, wherein said step (a) comprises incubating a mixture of said viral particle and said biological sample before adding said erythrocytes .

19. A method for determining the presence of an antibody in a biological sample, where said antibody binds selectively to a viral particle, the method comprising:

(a) incubating a mixture of erythrocytes, the viral particle, and the biological sample suspected of containing said antibody, under conditions permitting agglutination of the erythrocytes via interaction with said viral particle; and

(b) capturing with the aid of an optical device an image of said mixture, wherein the presence of an erythrocyte –viral particle cluster in said image indicates the occurrence of said agglutination and lack of detectable amount of said antibody, and wherein the absence of said cluster indicates the lack of said agglutination and the presence of detectable amount of said antibody

20. The method of claim 19, wherein the formation of said erythrocyte –viral particle cluster is determined by assessing center-to-center distance between individual erythrocytes captured in said image

21. The method of claim 19 or 20, wherein said step (a) comprising incubating a mixture of said viral particle and said biological sample prior to adding said erythrocytes .

22. A method for determining the presence of a viral particle in a biological sample, comprising:

(a) incubating a mixture of erythrocytes and a biological sample suspected of containing said viral particle, under conditions permitting agglutination of the erythrocytes via interaction with said viral particle; and

(b) detecting whether said agglutination occurs in said mixture, wherein the presence of said agglutination indicates the presence of said viral particle,

and wherein steps (a) – (b) take place in less than one hour.

23. A method for determining the presence of a viral particle in a biological sample, comprising:

(a) incubating a mixture of erythrocytes and a biological sample suspected of containing said viral particle, under conditions permitting agglutination of the erythrocytes via interaction with said viral particle; and

(b) capturing with the aid of an optical device an image of said mixture, wherein the presence of an erythrocyte –viral particle cluster in said image indicates the occurrence of said agglutination and the presence of detectable amount of said viral particle, and wherein the absence of said cluster indicates the lack of said agglutination and the lack of detectable amount of said viral particle.

24. A method for determining the effective immunization of a subject, comprising:

(a) incubating a mixture of erythrocytes, a viral particle, and a biological sample obtained from the subject that has been immunized with a first dosage of a first vaccine against the viral particle, under conditions permitting agglutination of the erythrocytes via interaction with said viral particle; and

(b) determining the concentration of an antibody against said virus in said sample based on the clusters formed by the agglutination of the erythrocytes,

and wherein said steps (a) – (b) take place in less than one hour.

25. A method for determining the effective immunization of a subject, comprising:

(a) incubating a mixture of erythrocytes, a viral particle, and a biological sample obtained from the subject that has been immunized with a first dosage of a first vaccine against the viral particle, under conditions permitting agglutination of the erythrocytes via interaction with said viral particle;

(b) capturing with the aid of an optical device an image of said mixture; and

(c) determining the concentration of an antibody against said viral in said biological sample based on the clusters formed by the agglutination of the erythrocytes,

wherein the presence of an erythrocyte –viral particle cluster in said image indicates the occurrence of said agglutination and lack of detectable amount of said antibody, and wherein the absence of said cluster indicates the lack of said agglutination and the presence of detectable amount of said antibody.

26. The method of claim 23 or 24, further comprising administration of a second dosage of said first vaccine against said viral particle to said subject if the concentration of said antibody is lower than a predetermined level.

27. The method of claim 23 or 24, further comprising administration of a second vaccine against said viral particle to said subject if the concentration of said antibody is lower than a predetermined level.

28. A kit, comprising: pre-fixed erythrocytes, a viral particle, and instructions for a user to use said kit for antibody or viral detection.

29. The method of any of claims 19, 23, or 25, wherein said image is a microscopic image.

30. A method for determining the presence of an antibody in a biological sample, wherein said antibody binds selectively to a viral particle, the method comprising:

(a) incubating a mixture of erythrocytes, the viral particle, and the biological sample suspected of containing said antibody, under conditions permitting agglutination of the erythrocytes via interaction with said viral particle;

(b) concurrent with or subsequent to (a), providing the mixture in a vessel having an opening at the top of the vessel and interior conical shape at the bottom of the vessel;

(c) tilting the vessel such that after tilting, at least a portion of the mixture is closer to the opening at the top of the vessel than prior to the tilting, and wherein at least a portion of the sample remains in the vessel after the tilting; and

(d) capturing with the aid of an optical device an image of said mixture, wherein the position of erythrocytes within the tilted vessel may be used to determine the presence or amount of said antibody in the sample.

31. A method for determining the presence of a viral particle in a biological sample, wherein said viral particle may be selectively bound by an antibody, the method comprising:

(a) incubating a mixture of erythrocytes, the antibody, and the biological sample suspected of containing said viral particle, under conditions permitting agglutination of the erythrocytes via interaction with said viral particle;

(b) concurrent with or subsequent to (a), providing the mixture in a vessel having an opening at the top of the vessel and interior conical shape at the bottom of the vessel;

(c) tilting the vessel such that after tilting, at least a portion of the mixture is closer to the opening at the top of the vessel than prior to the tilting, and wherein at least a portion of the sample remains in the vessel after the tilting; and

(d) capturing with the aid of an optical device an image of said mixture, wherein the position of erythrocytes within the tilted vessel may be used to determine the presence or amount of said viral particle in the sample.

32. The method of claims 30 or 31, wherein one or more zones for analysis are present or established within the vessel, and wherein optical signal is measured over each zone.

33. The method of claim 32, wherein the measured optical signal over the one or more zones may be used to determine the amount of agglutinated or unagglutinated erythrocytes in the sample.

34. The method of claims 30 or 31, wherein an axis for analysis is present or established within the vessel, and wherein optical signal is measured along the axis.

35. The method of claim 34, wherein the axis is through the center of a button portion and, if present, a teardrop portion of the packed red cells at the bottom of the vessel.

36. The method of claim 34 or 35, wherein the measured optical signal along the axis may be used to determine the amount of agglutinated or unagglutinated erythrocytes in the sample.

37. The method of claims 30 or 31, wherein packed red cells at the bottom of the vessel are identified, and the area or perimeter of the packed red cells is measured.

38. The method of claim 37, wherein the method further comprises using a pattern recognition method to identify a button and, optionally, teardrop region of the packed red cells.

39. The method of claim 37 or 38, wherein the area or perimeter of the packed red cells may be used to determine the amount of agglutinated or unagglutinated erythrocytes in the sample.

40. A method for determining the presence of an antibody in a biological sample, wherein said antibody binds selectively to an agglutinating particle, the method comprising:

(a) incubating a mixture of visualization particles, the agglutinating particle, and the biological sample suspected of containing said antibody, under conditions permitting agglutination of the visualization particle via interaction with said agglutinating particle; and

(b) detecting whether said agglutination occurs in said mixture, wherein the absence of said agglutination indicates the presence of said antibody,

wherein said steps (a) – (b) take place in less than one hour.

41. The method of claim 40, wherein said visualization particles are microspheres.

42. The method of claim 40 or 41, wherein said agglutinating particle comprises a virus, prion, or bacteria.

43. The method of any of claims 40-42, wherein said biological sample comprises plasma or serum.

44. The method of claim 43, wherein said plasma or serum is from a subject that has been administered with a vaccine against said agglutinating particle.

45. The method of any of claims 40-44, wherein said biological sample is pre-treated with neuraminidase.

46. The method of claim 45, wherein said treatment is carried out by incubating said biological sample with neuraminidase, and wherein the final concentration of the neuraminidase in the mixture is between 0.1 and 1.5 U/L.

47. The method of claim 46, wherein said treatment is carried out by incubating said sample with active neuraminidase for less than 30 minutes.

48. The method of any of claims 40-47, wherein said biological sample is serially diluted prior to step (a).

49. The method of any of claims 40-48, wherein said steps (a) – (b) take place in between about 30 to 60 minutes.

50. The method of any of claims 40-49, wherein the presence of said agglutination is evidenced by formation of visualization particle-agglutinating particle clusters, and wherein said clusters are captured in an imaging region of an optical device, and wherein said detecting step comprises:

(i) capturing a plurality of images of said clusters at different locations of said imaging region with the optical device; and

(ii) detecting the occurrence of said agglutination based on analysis of said images.

51. The method of claim 50, wherein said optical device comprises a camera.

52. The method of claim 50, wherein said optical device comprises a microscope.

53. The method of any of claims 50-52, wherein said imaging region resides in a microfluidic channel.

54. The method of any of claims 50-53, wherein said analysis comprises calculating the size of said clusters based on the center-to-center distance of individual erythrocytes captured in each of said images.

55. The method of any of claims 40-54, wherein said step (a) comprises incubating a mixture of said viral particle and said biological sample before adding said erythrocytes .

56. A method for determining the presence of an antibody in a biological sample, where said antibody binds selectively to an agglutinating particle, the method comprising:

(a) incubating a mixture of visualization particles, the agglutinating particle, and the biological sample suspected of containing said antibody, under conditions permitting agglutination of the visualization particle via interaction with said agglutinating particle; and

(b) capturing with the aid of an optical device an image of said mixture, wherein the presence of a visualization particle –agglutinating particle cluster in said image indicates the occurrence of said agglutination and lack of detectable amount of said antibody, and wherein the absence of said cluster indicates the lack of said agglutination and the presence of detectable amount of said antibody

57. The method of claim 56, wherein the formation of said visualization particle – agglutinating particle cluster is determined by assessing center-to-center distance between individual visualization particles captured in said image.

58. The method of claim 56 or 57, wherein said step (a) comprises incubating a mixture of said agglutinating particle and said biological sample prior to adding said visualization particle.

59. A method for determining the presence of an agglutinating particle in a biological sample, comprising:

(a) incubating a mixture of visualization particles and a biological sample suspected of containing said agglutinating particle, under conditions permitting agglutination of the visualization particle via interaction with said agglutinating particle; and

(b) detecting whether said agglutination occurs in said mixture, wherein the presence of said agglutination indicates the presence of said agglutinating particle,

and wherein steps (a) – (b) take place in less than one hour.

60. A method for determining the presence of an agglutinating particle in a biological sample, comprising:

(a) incubating a mixture of visualization particles and a biological sample suspected of containing said agglutinating particle, under conditions permitting agglutination of the visualization particle via interaction with said agglutinating particle; and

(b) capturing with the aid of an optical device an image of said mixture, wherein the presence of an visualization particle –agglutinating particle cluster in said image indicates the occurrence of said agglutination and the presence of detectable amount of said agglutinating particle, and wherein the absence of said cluster indicates the lack of said agglutination and the lack of detectable amount of said agglutinating particle.

61. A method for determining the effective immunization of a subject, comprising:

(a) incubating a mixture of visualization particles, an agglutinating particle, and a biological sample obtained from the subject that has been immunized with a first dosage of a first vaccine against the agglutinating particle, under conditions permitting agglutination of the visualization particles via interaction with said agglutinating particles; and

(b) determining the concentration of an antibody against said agglutinating particle in said sample based on the clusters formed by the agglutination of the visualization particles,

and wherein said steps (a) – (b) take place in less than one hour.

62. A method for determining the effective immunization of a subject, comprising:

(a) incubating a mixture of visualization particles, an agglutinating particle, and a biological sample obtained from the subject that has been immunized with a first dosage of a first vaccine against the agglutinating particle, under conditions permitting agglutination of the visualization particles via interaction with said agglutinating particle;

(b) capturing with the aid of an optical device an image of said mixture; and

(c) determining the concentration of an antibody against said agglutinating particle in said biological sample based on the clusters formed by the agglutination of the visualization particles,

wherein the presence of a visualization particle –agglutinating particle cluster in said image indicates the occurrence of said agglutination and lack of detectable amount of said antibody, and wherein the absence of said cluster indicates the lack of said agglutination and the presence of detectable amount of said antibody.

63. The method of claim 61 or 62, further comprising administration of a second dosage of said first vaccine against said agglutinating particle to said subject if the concentration of said antibody is lower than a predetermined level.

64. The method of claim 61 or 62, further comprising administration of a second vaccine against said agglutinating particle to said subject if the concentration of said antibody is lower than a predetermined level.

65. A kit, comprising: visualization particles, an agglutinating particle, and instructions for a user to use said kit for antibody or agglutinating particle detection.

66. The kit of claim 65, wherein the visualization particles are microspheres.

67. The method of any of claims 19, 23, 25, 56, 60, or 62 wherein said image is a microscopic image.

68. A method for determining the presence of an antibody in a biological sample, wherein said antibody binds selectively to an agglutinating particle, the method comprising:

(a) incubating a mixture of visualization particles, the agglutinating particle, and the biological sample suspected of containing said antibody, under conditions permitting agglutination of the visualization particle via interaction with said agglutinating particle;

(b) concurrent with or subsequent to (a), providing the mixture in a vessel having an opening at the top of the vessel and interior conical shape at the bottom of the vessel;

(c) tilting the vessel such that after tilting, at least a portion of the mixture is closer to the opening at the top of the vessel than prior to the tilting, and wherein at least a portion of the sample remains in the vessel after the tilting; and

(d) capturing with the aid of an optical device an image of said mixture, wherein the position of visualization particles within the tilted vessel may be used to determine the presence or amount of said antibody in the sample.

69. A method for determining the presence of an agglutinating particle in a biological sample, wherein the agglutinating particle may be selectively bound by an antibody, the method comprising:

(a) incubating a mixture of visualization particle, the antibody, and the biological sample suspected of containing said agglutinating particle, under conditions permitting agglutination of the visualization particles via interaction with said agglutinating particle;

(b) concurrent with or subsequent to (a), providing the mixture in a vessel having an opening at the top of the vessel and interior conical shape at the bottom of the vessel;

(c) tilting the vessel such that after tilting, at least a portion of the mixture is closer to the opening at the top of the vessel than prior to the tilting, and wherein at least a portion of the sample remains in the vessel after the tilting; and

(d) capturing with the aid of an optical device an image of said mixture, wherein the position of visualization particles within the tilted vessel may be used to determine the presence or amount of said agglutinating particle in the sample.

70. The method of claims 68 or 69, wherein one or more zones for analysis are present or established within the vessel, and wherein optical signal is measured over each zone.

71. The method of claim 70, wherein the measured optical signal over the one or more zones may be used to determine the amount of agglutinated or unagglutinated visualization particles in the sample.

72. The method of claims 68 or 69, wherein an axis for analysis is present or established within the vessel, and wherein optical signal is measured along the axis.

73. The method of claim 72, wherein the axis is through the center of a button portion and, if present, a teardrop portion of the packed visualization particles at the bottom of the vessel.

74. The method of claim 72 or 73, wherein the measured optical signal along the axis may be used to determine the amount of agglutinated or unagglutinated visualization particles in the sample.

75. The method of claims 68 or 69, wherein packed visualization particles at the bottom of the vessel are identified, and the area or perimeter of the packed visualization particles is measured.

76. The method claim 75, wherein the method further comprises using a pattern recognition method to identify a button and, optionally, teardrop region of the packed visualization particles.

77. The method of claim 75 or 76, wherein the area or perimeter of the packed visualization particles may be used to determine the amount of agglutinated or unagglutinated visualization particles in the sample.

78. The method of any of claims 19, 23, 25, 30, 31, 56, 60, 62, 68, or 69, wherein a plurality of images are collected, and said plurality of images are collected by video.

79. The method of any of claims 1-27, 29-64, or 67-78, wherein the method is performed at a point of service location.

80. A method of assaying for the agglutination of visualization particles in a mixture, comprising:

A) generating a mixture comprising the visualization particles and agglutinating particles under conditions permitting agglutination of the visualization particles via interaction with the agglutinating particles;

B) obtaining at least one image of the mixture; and

C) analyzing the image to obtain a measurement of the agglutination of the visualization particles in the mixture.

81. The method of claim 80, wherein the visualization particles are RBCs or microspheres.

82. The method of claim 80 or 81, wherein the agglutinating particles are viral particles or antibodies.

83. The method of any of claims 80-82, wherein the image is obtained with a CCD or CMOS image sensor.

84. The method of any of claims 80-83, wherein the image is obtained with an optical device.

85. The method of any of claims 80-84, wherein the agglutinating particles are provided in a biological sample from a subject.

86. The method of claim 85, wherein the biological sample comprises plasma or serum.

87. The method of claim 85, wherein the agglutinating particles are viral particles.

88. The method of claim 85, wherein the agglutinating particles are antibodies.

89. The method of claim any of claims 85-88, further comprising determining of the quantity of viral particles or antibodies in the sample.

90. The method of any of claims 80-89, wherein the mixture further comprises an antibody which specifically binds to at least one agglutinating particle of said agglutinating particles and inhibits the interaction of the agglutinating particle with a visualization particle of said visualization particles.

91. The method of claim 90, wherein the antibody is provided to the mixture in a biological sample from a subject.

92. The method of claim 91, wherein the biological sample comprises plasma or serum.

93. The method of claim 91 or 92, further comprising determining the quantity of the antibody in the sample.

94. The method of any of claims 80-93, wherein the image of the mixture is obtained within 1 hour of generating the mixture.

95. The method of any of claims 80-94, wherein the analyzing the image comprises identifying a region of interest (ROI) in the image.

96. The method of claim 95, wherein the ROI comprises imaged information of the mixture, said mixture comprising visualization particles and agglutinating particles.

97. The method of any of claims 80-96, wherein the measurement of the agglutination of the visualization particles in the mixture is a qualitative measurement of agglutination or non-agglutination of the visualization particles.

98. The method of any of claims 80-96, wherein the measurement of the agglutination of the visualization particles in the mixture is a quantitative measurement of degree of agglutination of the visualization particles.

99. The method of any of claims 80-98, wherein two or more images of the mixture are obtained.

100. The method of any of claims 80-99, wherein the agglutination is evidenced by the formation of clusters comprising visualization particles and agglutinating particles, and the step of analyzing the image comprises identifying clusters in the image.

101. The method of claim 100, further comprising determining the size or number of clusters in the image.

102. The method of claim 100, wherein the step of identifying clusters in the image comprises determining the distance between visualization particles in the image.

103. The method of claim 102, wherein the step of determining the distance between visualization particles in the image comprises determining the center-to-center distance between visualization particles in the image.

104. The method of any of claims 80-103, wherein the step of analyzing the image comprises determining the center-to-center distance between a first visualization particle and a second visualization particle in the image.

105. The method of claim 104, further comprising determining the location of the first visualization particle and the second visualization particle in the image.

106. The method of any of claims 100-105, wherein the step of identifying the clusters comprises identifying a first visualization particle and a second visualization particle, wherein the center-to-center distance between the first visualization particle and the second visualization particle is no greater than 1.5 times the diameter of either the first or second visualization particle.

107. The method of any of claims 100-106, wherein the step of identifying the clusters comprises identifying a first visualization particle and a second visualization particle, wherein the center-to-center distance between the first visualization particle and the second visualization particle is no greater than 12 um.

108. The method of any of claims 100-105, wherein the step of identifying the clusters comprises identifying at least three visualization particles, wherein each of the three visualization particles is positioned such that the center of the visualization particle is located no further than 15 um from the center of each of the other two visualization particles.

109. The method of any of claims 100-108, wherein the step of identifying the clusters comprises selecting a cut-off value distance, wherein visualization particles situated at a distance from each other which is less than the cut-off value distance are considered to be associated with each other.

110. The method of claim 109, wherein the step of selecting a cut-off value distance comprises calculating a radial distribution function for two or more visualization particles in the image.

111. The method of any of claims 80-110, wherein the step of analyzing the image comprises extracting a feature from a region of the image of the mixture.

112. The method of claim 111, wherein the step of extracting the feature comprises analyzing the texture of the mixture.

113. The method of claim 112, wherein the step of analyzing the texture of the mixture comprises analyzing the image with a local binary patterns operator.

114. The method of claim 112 or 113, wherein the step of extracting the feature comprises analyzing the intensity of a signal in one or more color channels in a region of the image.

115. The method of claim 113, wherein the step of analyzing the texture of the mixture comprises inputting information obtained from the local binary patterns operator into an algorithm which has been previously trained with local binary patterns information from one or more images of a mixture of known agglutination status.

116. The method of any of claims 80-115, wherein the step of analyzing the image comprises comparing feature extraction information from the image of the mixture with feature extraction information from an image of a control mixture of known agglutination status, said control mixture comprising visualization particles and agglutinating particles.

117. The method of any of claims 80-116, wherein steps A) - C) are performed in one hour or less.